UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. Undetermined quantities of boxes of Signature Edition Gold infusion pumps, articles of device, each box containing one infusion pump, Model numbers 7130, 7131, 7230, and 7231, labeled in part: (box) "*** ALARIS™ MEDICAL SYSTEMS *** ALARIS Medical Systems, Inc. San Diego, CA USA *** SN ***" (pump) "*** ALARIS *** Signature Edition® GOLD Infusion System *** ALARIS *** MEDICAL SYSTEMS *** SAN DIEGO, CA ***," and CARDINAL HEALTH 303, INC., a corporation, and DWIGHT WINSTEAD, DAVID L. SCHLOTTERBECK, and DONALD M. ABBEY, individuals, Defendants.	)	Civil No. 06 CV 1706 BEN (NLS) **AMENDED CONSENT DECREE FOR CONDEMNATION AND PERMANENT INJUNCTION**

WHEREAS, on August 23, 2006, Plaintiff, the United States of America, by and through its attorneys and on behalf of the United States Food and Drug Administration ("FDA"), filed a verified complaint for forfeiture against certain articles that were in the possession of Cardinal Health 303, Inc. ("Cardinal 303"), located at 9190 Activity Road, San Diego, California. The complaint alleges, among other things, that the above-captioned articles (the "Seized Articles")

are adulterated under Sections 501(c) and 501(h) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 351(c) and 351(h). Pursuant to the Warrant for Arrest issued by this Court, the United States Marshal for this district ("Marshal") seized the articles of device at Cardinal 303's facility on August 25, 2006. Cardinal 303, formerly known as ALARIS Medical Systems, Inc. ("Claimant"), filed a statement of interest signed by Dwight Winstead, President and Chief Operating Officer, for the Seized Articles on September 6, 2006.

WHEREAS, the complaint alleges that the Seized Articles are: (1) adulterated within the meaning of the Act, 21 U.S.C. § 351(c), in that their quality falls below that which they purport and are represented to possess; and (2) adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice ("CGMP") and the Quality System regulation ("QS regulation"), 21 C.F.R. Part 820.

WHEREAS, Cardinal 303, Dwight Winstead (Cardinal 303's President and Chief Operating Officer), David L. Schlotterbeck (Cardinal 303's Chairman and Chief Executive Officer), and William H. Murphy (Cardinal 303's Senior Vice President of Quality and Regulatory Affairs), without admitting the allegations in the complaint, agreed to the entry of a Consent Decree for Condemnation and Permanent Injunction entered by this Court on February 7, 2007 ("2007 Decree"). The 2007 Decree included injunctive provisions relating to the design, manufacture, processing, packing, repacking, labeling, holding, distributing, or importation into the United States of America of all models of Cardinal 303's Signature Edition infusion pumps ("SE infusion pumps"), requiring Defendants to ensure that their SE infusion pump manufacturing operations comply with the Act and that the SE infusion pumps currently in use in the United States are brought into compliance with the Act. After the 2007 Decree was entered, Defendants have complied with certain of its provisions and have asserted to FDA that they are complying with other provisions.

WHEREAS, from January 8 to February 1, 2008, while the 2007 Decree was in effect, the FDA inspected Cardinal 303's infusion pump operations, and specifically Cardinal 303's

Alaris System, formerly known as Medley, infusion pumps, and alleged, based upon that inspection, that the Alaris System infusion pumps are (a) adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, and facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with CGMP and the QS regulation, 21 C.F.R. Part 820, and (b) misbranded within the meaning of the Act, 21 U.S.C. § 352(t)(2), for failure to submit reports of correction and removals and medical device reports. Based upon this inspection, FDA determined that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering, and causing to be introduced or delivered for introduction, into interstate commerce, their infusion pumps (articles of device within the meaning of 21 U.S.C. § 321(h)) that are adulterated within the meaning of 21 U.S.C. § 351(h) and misbranded within the meaning of 21 U.S.C. § 352(t)(2); and that Defendants violate the Act, 21 U.S.C. § 331(k), by doing or causing any act that results in the adulteration, within the meaning of 21 U.S.C. § 351(h), and the misbranding, within the meaning of 21 U.S.C. § 352(t)(2), of such articles of device while they are held for sale after the shipment of one or more of their components in interstate commerce.

WHEREAS, for the reasons set forth above, the 2007 Decree is hereby amended as follows.

WHEREAS, Defendant William H. Murphy is no longer Cardinal 303's Senior Vice President of Quality and Regulatory Affairs and this position was filled by and is currently held by Donald M. Abbey. Therefore, Defendant Donald M. Abbey shall be substituted for Defendant William H. Murphy.

WHEREAS, Cardinal 303, Dwight Winstead, David L. Schlotterbeck, and Donald M. Abbey (collectively, "Defendants" unless otherwise specified), without admitting the allegations in the complaint or this Amended Consent Decree for Condemnation and Permanent Injunction ("this Decree"), have appeared, have waived the filing and service of an amended complaint seeking further injunctive relief, and, before any testimony has been taken, have consented to the entry of this Decree.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter herein and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. §§ 1331 and 1345 and 21 U.S.C. §§ 332 and 334. Venue is proper in this district under 28 U.S.C. §§ 1391(b)-(c) and 1395.

2. The in rem seizure complaint states a claim for relief against the Seized Articles under the Act, 21 U.S.C. §§ 301-397.

SEIZURE PROVISIONS

3. Defendant Cardinal 303 has made a claim as to all of the Seized Articles. Defendant Cardinal 303 further affirms that it shall indemnify and hold the United States harmless should any other party or parties hereafter file or seek to file a statement of interest or right to intervene in this action, or seek to defend or obtain any part of the Seized Articles.

4. The complaint alleges that the Seized Articles violate the Act in the following ways:

A. The Seized Articles (Signature Edition Gold infusion pumps; model numbers 7130, 7131, 7230, 7231) are adulterated within the meaning of the Act, 21 U.S.C. § 351(c), in that their quality falls below that which they purport and are represented to possess; and

B. The Seized Articles (Signature Edition Gold infusion pumps; model numbers 7130, 7131, 7230, 7231) are adulterated within the meaning of the Act, 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with CGMP and the QS regulation as promulgated under 21 C.F.R. Part 820.

5. The Seized Articles are hereby condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

6. The United States shall recover from Defendant Cardinal 303 all court costs, fees, and storage and other proper expenses, and such further costs for which Defendant Cardinal 303 is liable pursuant to 21 U.S.C. § 334(e) with respect to the Seized Articles. Defendant Cardinal

303 shall pay these costs within fifteen (15) calendar days of receiving written notice from the FDA of such costs.

7. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) calendar days of the entry of this Decree, Defendant Cardinal 303 shall execute and file with the clerk of this Court a good and sufficient penal bond (the "Bond") with surety in the amount of 3.6 million dollars ($3,600,000). The Bond shall be in a form acceptable to the clerk of this Court and payable to the United States of America, and conditioned on Defendants abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding.

8. A. Within thirty (30) calendar days of the entry of this Decree, and after filing the Bond with this Court as provided in paragraph 7 of this Decree, Defendant Cardinal 303 shall give written notice to FDA that Defendant Cardinal 303, at its own expense, is prepared to attempt to bring the Seized Articles into compliance with the law under FDA's supervision. This notice shall include a detailed written plan describing Defendant Cardinal 303's proposal to bring the Seized Articles into compliance with the Act. Defendants shall not attempt to bring the Seized Articles into compliance until Defendant Cardinal 303 has submitted a written plan to FDA and FDA has notified Defendant Cardinal 303 in writing that its plan is acceptable. FDA's decision regarding the adequacy of the reconditioning proposal shall constitute final agency action.

B. FDA shall notify Defendant Cardinal 303 in writing within forty-five (45) calendar days of FDA's receipt of Defendant Cardinal 303's reconditioning plan whether the reconditioning plan is acceptable in whole or in part. If the reconditioning plan is acceptable with regard to some of the Seized Articles and not others, FDA shall specify those Seized Articles for which the reconditioning plan is acceptable. If FDA notifies Defendant Cardinal 303 in writing that some or all of the reconditioning plan is unacceptable, FDA shall state the basis for such determination. Defendant Cardinal 303 shall then submit, within twenty (20) calendar days of receipt of FDA's letter, either a revised reconditioning plan for those Articles

for which the initial plan was unacceptable or a plan to destroy those Articles as set forth below. FDA shall respond in writing within thirty (30) calendar days of its receipt of Defendant Cardinal 303's revised reconditioning plan to notify Defendants as to whether the revised plan is acceptable. If Defendant Cardinal 303 has not submitted a revised reconditioning plan within twenty (20) calendar days of receipt of FDA's letter, or if FDA finds that the revised reconditioning plan is unacceptable, Defendants shall cause that portion of the Seized Articles for which no revised reconditioning plan was submitted or for which the revised reconditioning plan was deemed unacceptable, to be promptly destroyed at Defendant Cardinal 303's expense and under the supervision of an FDA representative. If FDA finds that Defendant Cardinal 303's revised reconditioning plan is unacceptable, in whole or in part, Defendants may challenge that decision under the terms set forth in paragraph 33. Defendants may execute any portion of the initial or revised reconditioning plan that was found acceptable to FDA in accordance with the applicable provisions of the Decree.

C. Defendants shall not dispose of the Seized Articles or any part of them in a manner contrary to the provisions of the Act, or any other federal law, or of the laws of any state or territory (as defined in the Act) in which they are disposed. All Seized Articles that are not successfully reconditioned as provided by this Decree shall be destroyed by Defendants at Defendant Cardinal 303's expense under supervision of an FDA representative, and Defendant Cardinal 303 shall pay to the United States all costs incurred in supervising the destruction of such articles, at rates specified in paragraph 26 of this Decree.

D. Following Defendant Cardinal 303's receipt of written authorization to commence attempting to bring the Seized Articles into compliance with the Act and following the payment of costs pursuant to paragraph 6 and the posting of the Bond by Defendant Cardinal 303 as required by paragraph 7 of this Decree, the Marshal shall, upon receiving written notice from FDA, release those Articles that are specified in FDA's notice to Defendant Cardinal 303 from his custody to the custody of Defendant Cardinal 303 for the purpose of attempting to bring the Articles into compliance with the law.

E. Defendants shall at all times, until the Seized Articles have been brought into compliance with the law as determined by FDA or destroyed under FDA supervision, retain the Seized Articles intact for examination or inspection by FDA in a place made known to and approved by FDA, and shall retain the records or other proof necessary to establish the identity of the Seized Articles.

F. If requested by FDA, Defendant Cardinal 303 shall furnish duplicate copies of invoices of sale of any released devices, or other evidence of disposition as FDA may request.

G. Within ninety (90) calendar days of receiving approval and/or rejection of the reconditioning plan pursuant to paragraph 8(B), Defendants shall either destroy the Seized Articles at Defendant Cardinal 303's sole expense under the supervision of the FDA representative or complete their attempt to bring the Seized Articles into compliance with the law in a manner set forth in the reconditioning plan found acceptable to FDA. Defendant Cardinal 303 shall reimburse the United States for the costs of supervising the reconditioning and/or destruction of the Seized Articles within twenty (20) calendar days of receiving an invoice for such costs at the rates listed in paragraph 26. Defendant Cardinal 303 shall also bear all costs of destruction and be responsible for ensuring that such destruction is carried out in a manner that complies with the provisions of the Act, other federal laws, and the laws of any state or territory (as defined in the Act) in which they are disposed. Within twenty-five (25) calendar days of receiving Defendant Cardinal 303's written notice to FDA of completion of the attempt to bring the Seized Articles into compliance with the Act and/or destruction of the Seized Articles, FDA shall provide Defendant Cardinal 303 with an invoice for the costs of supervising such attempt and/or destruction. Defendant Cardinal 303 shall pay those costs within twenty (20) calendar days of receiving FDA's invoice. Upon receipt of such payment from Defendant Cardinal 303, FDA will notify the United States Attorney for this district that Defendants have brought the Seized Articles into compliance with the law and/or destroyed the articles, and that Defendant Cardinal 303 has paid the costs set forth in FDA's invoice.

H. The United States Attorney for this district, upon being advised by FDA that the foregoing conditions of this Decree have been performed, shall transmit such information to the clerk of this Court, whereupon the Bond given in this proceeding shall be canceled and discharged.

9. If Defendants fail to abide by and perform all of the terms and conditions of this Decree, or of the Bond, or of such further order or decree as may be entered in this proceeding, then the Bond posted as provided in paragraph 7 of this Decree shall, on motion of the Plaintiff in this proceeding, be forfeited in its entirety and judgment entered in favor of Plaintiff. In addition, if Defendants breach any term or condition of this Decree or such further order or decree as may be entered in this proceeding, then Defendant Cardinal 303 shall, at its own expense, immediately return the Seized Articles to the Marshal or otherwise dispose of them pursuant to an order of this Court. Following return of the Seized Articles to the United States, the Marshal shall destroy the Seized Articles and make due return to this Court. In the event that destruction of the Seized Articles by the Marshal becomes necessary pursuant to this paragraph, Defendant Cardinal 303 shall be responsible for all costs of storage and disposition that are incurred by the United States.

10. Defendants shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of the Seized Articles, or any part thereof, until: (a) FDA has had free access to the articles in order to take any samples or make any tests or examinations that FDA deems necessary; (b) FDA has notified Defendants in writing that any reconditioning to be conducted in accordance with the reconditioning proposal in paragraph 8(A) is complete and that the reconditioned devices comply with the Act, its implementing regulations, and this Decree; and (c) FDA has notified the United States Attorney for this district that Defendants have completed their attempt to bring the articles into compliance with the law in accordance with paragraph 8(G).

INJUNCTIVE PROVISIONS - SE INFUSION PUMPS

11. Paragraphs 12-14 shall apply only to all models of Defendant Cardinal 303's SE

infusion pumps, including all components and parts thereof.

12. Upon entry of this Decree, Defendants, and each and all of Defendant Cardinal 303's officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of the contents of this Decree by personal service or otherwise, are permanently enjoined, pursuant to 21 U.S.C. § 332(a), from designing, manufacturing, processing, packing, repacking, labeling, holding, distributing, or importing into the United States of America all models of its SE infusion pumps, unless and until:

A. The methods, facilities, and controls used to design, manufacture, process, pack, repack, label, hold, and distribute the SE infusion pumps are established, operated, and administered in compliance with 21 U.S.C. § 351(h) and 21 C.F.R. Part 820.

B. Defendant Cardinal 303 retains at its expense an independent person or persons (the "Expert"), who is qualified by education, training, and experience to conduct inspections of any Defendant Cardinal 303's facilities that design, manufacture, process, pack, repack, label, hold, or distribute the SE infusion pumps or any component thereof (hereafter, "SE infusion pump facilities"), and to review procedures and methods for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing SE infusion pumps, to determine whether their methods, facilities, and controls are operated and administered in conformity with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, and this Decree. The Expert shall be without personal or financial ties (other than a consulting agreement between the parties) to any officer or employee of Defendant Cardinal 303 or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) calendar days of retaining such Expert or ten (10) calendar days after the date this Decree is entered, whichever is later.

C. The Expert shall perform a comprehensive inspection of Defendant Cardinal 303's SE infusion pump facilities and manner of operation and certify in writing to FDA: (1) that he or she has inspected Defendant Cardinal 303's SE infusion pump facilities,

processes, and controls; (2) whether Defendants have corrected all deviations set forth in FDA's Inspectional Observations (Form FDA 483) from all prior FDA inspections since 2000; and (3) based upon this comprehensive inspection, whether Defendant Cardinal 303's infusion pump operations are operated in conformity with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, and this Decree. The Expert's certification report shall encompass, but not be limited to, an evaluation of the following:

i. Defendant Cardinal 303's compliance with 21 U.S.C. §§ 351(h), 360j(f)(1), and 21 C.F.R. Part 820;

ii. Defendant Cardinal 303's procedures for its Corrective and Preventive Action ("CAPA") system including, but not limited to: analyzing quality data to identify existing and potential causes of nonconforming product and other quality problems; investigating the causes of nonconformities relating to product, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; verifying or validating corrective and preventative actions to ensure that such actions are effective and do not adversely affect the finished device; implementing and recording changes in methods and procedures as needed to correct and prevent quality problems; conducting and documenting adequate failure investigations; and implementing an effective complaint handling system;

iii. Defendant Cardinal 303's design control system, including the design change control process and performance of risk analysis;

iv. Steps taken by Defendant Cardinal 303 to identify the root causes for the key bounce problem in the SE infusion pumps and an evaluation of whether Defendant Cardinal 303 has implemented appropriate steps to correct and prevent key bounce;

v. Defendant Cardinal 303's protocols and documentation for all design validation for the SE infusion pump, including any design changes made to the software; and

vi. Defendant Cardinal 303's procedures to adequately inspect and test incoming components used in the SE infusion pumps to verify conformance to product

specifications.

D. Defendants report to FDA in writing the actions that they have taken to: (1) correct all deviations set forth in FDA's Inspectional Observations (Form FDA 483) from all prior FDA inspections since 2000; and (2) ensure that the methods used in, and the facilities and controls used for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing SE infusion pumps are operated and administered and will be continuously operated and administered in conformity with 21 U.S.C. § 351(h), 21 C.F.R. Part 820, and this Decree.

E. Within forty-five (45) calendar days of receipt of the report under paragraph 12(D), FDA may, in its discretion and without prior notice, commence an inspection of Defendant Cardinal 303's SE infusion pump facilities to evaluate the report, determine whether the requirements of this Decree have been met, and whether Defendant Cardinal 303's SE infusion pump facilities are otherwise operated in conformity with 21 U.S.C. § 351(h) and 21 C.F.R. Part 820.

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 12(A)-(E).

G. Notwithstanding subparagraphs (A)-(F) of this paragraph, Defendant Cardinal 303 may continue its service and repair operations of the SE infusion pumps so long as it: (1) affixes the warning label relating to the key bounce problem referred to in Defendant Cardinal 303's August 15, 2006, voluntary recall letter to any such pumps that are returned to Defendant Cardinal 303 for service without such a label; (2) sends a notification along with all such pumps being returned from service, stating that the device has not been repaired or serviced for any problem relating to the key bounce problem; and (3) provides FDA, on a monthly basis, with the number of pumps serviced, including serial and model numbers of the pumps, and the location of the facilities where the pumps are returned. The notification requirement set forth in clauses (1) and (2) of this paragraph shall not apply with respect to any serviced or repaired SE infusion pump where the key bounce problem has been previously corrected or modified

pursuant to paragraphs 8(G) or 14.

13. Paragraph 12 of this Decree shall not apply to the following:

A. Any SE infusion pumps or components thereof, or parts or accessories thereto, manufactured, processed, packaged, labeled, held for sale, or introduced into interstate commerce solely for export from the United States, provided that the applicable requirements of 21 U.S.C. § 381(e) have been satisfied with respect to any such device, component, part, or accessory.

B. Any SE infusion pumps or components thereof, or parts or accessories thereto, whose manufacture or processing is not intended for human use and is undertaken for the *sole* purpose of developing, testing, verifying, or validating design changes or modifications in accordance with 21 C.F.R. §§ 820.75, 820.1(a)(3), and 820.30(f)-(g), and revised production and process controls, revised manufacturing procedures, or the adequacy of corrective and preventive actions. SE infusion pumps made or processed under this subparagraph may not be commercially distributed in interstate commerce.

C. Any SE infusion pumps or components thereof designed, manufactured, imported, distributed, installed or serviced *solely* for the purpose of complying with the requirements of paragraphs 12(G) and 14, provided that such SE infusion pumps comply with the requirements set forth in the corrective action plan after its approval by FDA under paragraph 14.

14. A. Within twenty (20) calendar days after entry of this Decree, Defendants are required to submit to FDA in writing a detailed Corrective Action Plan to bring all SE infusion pumps currently in use in the United States by physicians, hospitals, pharmacies, and other users/facilities into compliance with the Act, its implementing regulations, and this Decree, and shall also address specific SE infusion pump units that can no longer be brought into compliance because they are beyond their useful life. The written Corrective Action Plan shall include, among other things: (1) identification of the root causes of any failures in the SE infusion pumps of which Defendants are aware or should be aware; (2) a description and

supporting documentation for any and all upgrades, modifications and/or actions necessary to correct these failures in the SE infusion pumps; (3) the testing conducted to verify and validate such upgrades and/or modifications; (4) the projected date on which Defendants will implement and complete the Corrective Action Plan for SE infusion pumps; (5) the manner in which the upgrades and/or modifications will be made to the SE infusion pumps; (6) whether SE infusion pumps will be recalled to implement corrective actions; and (7) a clear statement whether Defendants believe the proposed upgrades and/or modifications to the SE infusion pumps proposed in the Corrective Action Plan require premarket clearance from FDA, the reasons for that belief, and whether premarket clearance has been sought and obtained by Defendant Cardinal 303.

B. Defendants shall not initiate the Corrective Action Plan until FDA has first provided Defendants with written authorization to proceed with all or a portion of the Corrective Action Plan. FDA shall respond in writing within forty-five (45) calendar days of FDA's receipt of Defendants' Corrective Action Plan and notify Defendant Cardinal 303 in writing whether the proposed Corrective Action Plan is acceptable in whole or in part. If the Corrective Action Plan is acceptable with regard to some of the SE infusion pumps and not others, FDA shall specify those SE infusion pumps for which the Corrective Action Plan is acceptable. If FDA finds some or all of the Corrective Action Plan unacceptable, it shall state in writing the basis for finding specific portions of the proposed Corrective Action Plan unacceptable, and Defendants shall submit a revised Corrective Action Plan in writing within twenty (20) calendar days of receipt of FDA's response. FDA shall respond in writing within thirty (30) calendar days of FDA's receipt of Defendants' revised Corrective Action Plan and notify Defendant Cardinal 303 in writing whether the revised plan is acceptable. FDA's decision regarding the adequacy of Defendants' Corrective Action Plan or revised Corrective Action Plan shall be final.

C. Defendants shall commence the implementation of those portions of the initial and/or revised Corrective Action Plan that were found acceptable by the FDA within thirty

(30) calendar days of receiving FDA's written authorization of the initial and/or revised Corrective Action Plan. Defendants shall, beginning one month after the date on which implementation of the Corrective Action Plan, in whole or in part, has begun, and continuing until its completion, submit to FDA monthly written progress reports updating the status of the Corrective Action Plan. Defendants shall use their best efforts to locate all SE infusion pumps in use by health care professionals in the United States and to obtain the cooperation of such users to implement the corrective actions required by this paragraph. Defendants' methods to locate all SE infusion pumps, including both the SE Gold infusion pumps and other models of SE infusion pumps, shall be detailed in the Corrective Action Plan and be appropriate based upon variations in the devices' distribution. If Defendants have not obtained FDA's authorization for the Corrective Action Plan, in whole or in part, within twelve (12) months after the date this Decree is entered, FDA may take any action(s) it deems appropriate under paragraph 22 of this Decree.

INJUNCTIVE PROVISIONS - ALARIS SYSTEM AND ALL OTHER INFUSION PUMPS (EXCLUDING SE INFUSION PUMPS)

15. Paragraphs 16-17 shall apply to all infusion pumps, other than the SE infusion pumps, manufactured by or for Defendant Cardinal 303, including, but not limited to, Alaris System infusion pumps (formerly known as the Alaris Medley infusion pumps manufactured by Alaris Medical Systems), Med System III infusion pumps, and Gemini infusion pumps, including all components and parts thereof (collectively referred to hereafter as "Alaris System and all other infusion pumps").

16. A. Within ten (10) calendar days after the entry of this Decree, Defendant Cardinal 303 shall retain at its expense an independent person or persons (the "Expert"), who is qualified by education, training, and experience to conduct inspections of all Defendant Cardinal 303 facilities that design, manufacture, process, pack, repack, label, hold, or distribute Alaris System and all other infusion pumps (hereafter, "Alaris System and all other infusion pump facilities"), and to review procedures and methods for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing Alaris System and all other infusion

pumps, to determine whether the methods, facilities, and controls used to make such infusion pumps are operated and administered in conformity with CGMP, 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806, and 820, and this Decree. The Expert shall be without personal or financial ties (other than a consulting agreement between the parties) to any of Cardinal 303's officers or employees or their immediate families. Defendants shall notify FDA in writing of the identity of the Expert within ten (10) calendar days of retaining that person or the date this Decree is entered, whichever is later. This Expert may be the same person identified in paragraph 12(B) above.

B. Within one hundred (100) calendar days after the entry of this Decree, the Expert shall complete a comprehensive inspection of Defendant Cardinal 303's Alaris System and all other infusion pump facilities and manner of operation and certify in writing to FDA: (1) that he or she has inspected Defendant Cardinal 303's Alaris System and all other infusion pump facilities, processes, and controls; (2) whether Defendants have corrected all deviations set forth in FDA's Inspectional Observations (Form FDA 483) from all prior FDA inspections since 2000 (including the Form FDA 483 dated February 1, 2008) and all other deviations of which they become aware; and (3) based upon this comprehensive inspection, whether Defendant Cardinal 303's infusion pump operations are operated in conformity with CGMP, 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806, and 820, and this Decree. The Expert's certification report shall encompass, but not be limited to, an evaluation of the following:

i. Defendant Cardinal 303's compliance with 21 U.S.C. §§ 351(h), 360j(f)(1), and 352(t)(2), and 21 C.F.R. Parts 803, 806, and 820;

ii. Defendant Cardinal 303's procedures for its Corrective and Preventive Action ("CAPA") system including, but not limited to: analyzing quality data to identify existing and potential causes of nonconforming products and other quality problems; investigating the causes of nonconformities relating to products, processes, and the quality system; identifying the action(s) needed to correct and prevent recurrence of nonconforming products and other quality problems; verifying or validating corrective and preventative actions

to ensure that such actions are effective and do not adversely affect the finished devices; implementing and recording changes in methods and procedures as needed to correct and prevent quality problems; conducting and documenting adequate failure investigations; and implementing an effective complaint handling system;

iii. Defendant Cardinal 303's design controls including, but not limited to, design changes, design validation, the performance of risk analyses, protocols and documentation for all design validation for the Alaris System and all other infusion pumps, including any design changes made to the software;

iv. Steps taken by Defendant Cardinal 303 to identify the root causes for the (a) bent, broken, missing, or nested occluder spring problem; (b) U3, U6, U9, and U19 chip socket problem; (c) IUI connector problem; (d) broken or cracked door problem; and (e) all other identified deficiencies in the Alaris System and all other infusion pumps, including an evaluation of whether Defendant Cardinal 303 has implemented appropriate steps to correct and prevent such deficiencies and the recurrence of such deficiencies;

v. Defendant Cardinal 303's procedures to adequately inspect and test incoming products used in the Alaris System and all other infusion pumps to verify conformance to product specifications and final product release testing;

vi. Defendant Cardinal 303's procedures for identifying employee training needs to ensure that all personnel are trained to adequately perform their assigned responsibilities;

vii. Defendants have represented to FDA and to this Court that: (a) the Gemini infusion pump has not been distributed in interstate commerce or manufactured since July 27, 2007; and (b) with the exception of one customer, Cardinal 303 has ceased servicing the Gemini infusion pumps and has ceased distributing in interstate commerce Gemini infusion pump parts as of the date of the entry of this Decree. Based upon these representations, notwithstanding the requirements set forth in subparagraph 16(B) above, the Gemini infusion pump is only subject to the post-market requirements of 21 C.F.R. Parts 803, 806, and 820

(including 21 C.F.R. §§ 820.100 (Corrective and Prevention Action), 820.198 (Complaint Files), and 820.200 (Servicing)). If the United States notifies Defendants that it has learned after the entry of this Decree that any of the representations in this subparagraph are inaccurate, the Gemini infusion pumps shall be subject to all of the requirements set forth in subparagraph 16(B) above. In addition, if the Gemini infusion pumps are distributed in interstate commerce or manufactured at any point in the future, the Gemini infusion pumps shall be subject to all of the requirements set forth in subparagraph 16(B) above;

viii. To avoid duplication of efforts, the Expert's certification report may refer, if appropriate, to a prior certification report completed pursuant to paragraph 12(C) above. If a reference to a prior certification report is made, the Expert shall identify the specific page(s) within the referenced report where the supporting evidence is located. In such case, the Expert may submit one certification to the FDA that indicates which specific requirements for the Expert certification outlined in 16(B) above have been met.

C. Within twenty (20) calendar days after the date of the Expert's certification, Defendants shall report to FDA, in writing, the actions that they have taken to: (1) correct all deviations set forth in FDA's Inspectional Observations (Form FDA 483) from all prior FDA inspections since 2000; and (2) ensure that the methods used in, and the facilities and controls used for designing, manufacturing, processing, packing, repacking, labeling, holding, and distributing the Alaris System and all other infusion pumps are operated and administered and will be continuously operated and administered in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806, and 820, and this Decree.

D. Within forty-five (45) calendar days of receipt of the report under paragraph 16(C), FDA may, in its discretion and without prior notice, commence an inspection of Defendant Cardinal 303's Alaris System and all other infusion pump facilities to determine whether the requirements of this Decree have been met, and whether Defendant Cardinal 303's Alaris System and all other infusion pump facilities are otherwise operated in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2) and 21 C.F.R. Parts 803, 806, and 820. Following this

inspection, FDA will notify Defendants of its findings ("FDA's Notice"). If FDA notifies Defendants of any violations of 21 U.S.C. §§ 351(h) and/or 352(t)(2) and/or 21 C.F.R. Parts 803, 806, and/or 820 and/or this Decree, Defendants shall, within forty-five (45) calendar days of receipt of FDA's Notice, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving FDA's Notice, Defendants believe that correction of any observation will take longer than forty-five (45) calendar days, Defendants shall, within ten (10) calendar days of receipt of FDA's Notice, propose a schedule for completing corrections for any such observation ("Correction Schedule") and provide justification for the additional time. The Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections within forty-five (45) calendar days of FDA's Notice or according to an FDA-approved Correction Schedule, if one exists.

E. If Defendants fail to complete all corrections pursuant to the terms of this paragraph, FDA may apply the provisions set forth in paragraph 22 of this Decree.

17. A. Within sixty (60) calendar days after entry of this Decree, Defendants shall submit to FDA in writing a detailed corrective action plan to bring the Alaris System and all other infusion pumps currently in use in the United States by physicians, hospitals, pharmacies, and other users/facilities into compliance with the Act, its implementing regulations, and this Decree ("2009 Corrective Action Plan"). The 2009 Corrective Action Plan shall also address specific infusion pump units that can no longer be brought into compliance. For those devices that can no longer be brought into compliance, the 2009 Corrective Action Plan shall address the final disposition of such devices. The written 2009 Corrective Action Plan shall meet the requirements of 21 C.F.R. § 820.100, and shall be developed using the following elements: analysis of all processes, work operations, concessions, quality audit reports, quality records, service records, complaints, medical device reports, returned products, and any other sources of quality data to identify existing and potential causes of nonconforming product or other quality problems associated with the Alaris System and all other infusion pumps.

The written 2009 Corrective Action Plan shall include, for each model, among other things: (1) a detailed description of the investigation into and identification of the root causes of all failures in the Alaris System and all other infusion pumps which Defendants are aware or should be aware; (2) a description and supporting documentation for any and all upgrades, modifications, and actions necessary to correct and prevent recurrence of these failures with the Alaris System and all other infusion pumps; (3) a detailed description of the verification or validation conducted to ensure that such action meets the device specifications, is effective, and does not adversely affect the finish device; (4) the method(s) by which information related to these failures is disseminated to those directly responsible for ensuring the compliance of the Alaris System and all other infusion pumps; (5) the projected date on which Defendants shall implement the 2009 Corrective Action Plan; (6) the manner in which the upgrades and modifications shall be made to the Alaris System and all other infusion pumps; (7) a statement whether any Alaris System and all other infusion pump(s) will be recalled to implement corrective actions and, if so, which products; and (8) a clear statement as to whether premarket clearance for each model has been sought and obtained by Defendant Cardinal 303.

B. In developing this 2009 Corrective Action Plan, Defendants shall use a risk-based approach for repairing, reconditioning, and replacing the Alaris System and all other infusion pumps to minimize interruption of patient therapy and customer operations. As part of this approach, the 2009 Corrective Action Plan shall: (i) identify which facilities receive priority for correcting any Alaris System and all other infusion pumps that are defective; (ii) clearly state the criteria that Defendants shall use to establish this priority; (iii) identify "high risk" customers for whom the Alaris System and all other infusion pumps are critical to the operation of their facility and customers who do not have alternative or replacement devices; and (iv) include a plan to address requests for service from customers that have been identified as "lower risk." Defendant Cardinal 303 shall pay all costs associated with the 2009 Corrective Action Plan, including, but not limited to, all shipping, handling, repair, and replacement costs.

C. Defendants shall not initiate the 2009 Corrective Action Plan until FDA

has first provided them with written authorization to proceed with all or a portion of the 2009 Corrective Action Plan. FDA will respond in writing within forty (40) calendar days of FDA's receipt of Defendants' 2009 Corrective Action Plan and notify Defendant Cardinal 303 in writing whether the proposed 2009 Corrective Action Plan is acceptable, in whole or in part. If the 2009 Corrective Action Plan is acceptable with regard to some of the Alaris System and all other infusion pumps but not others, FDA shall specify those infusion pumps for which the 2009 Corrective Action Plan is acceptable. If FDA finds some or all of the 2009 Corrective Action Plan unacceptable, it shall state in writing the basis for finding specific portions of the proposed 2009 Corrective Action Plan unacceptable, and Defendants shall submit a revised 2009 Corrective Action Plan in writing within twenty (20) calendar days of receipt of FDA's response. FDA shall respond in writing within forty (40) calendar days of FDA's receipt of Defendants' revised 2009 Corrective Action Plan and notify Defendant Cardinal 303 in writing whether the revised plan is acceptable, in whole or in part. FDA's decision regarding the adequacy of Defendants' 2009 Corrective Action Plan or revised 2009 Corrective Action Plan shall be final. If FDA has not authorized the implementation of the 2009 Corrective Action Plan, in whole or in part, within twelve (12) months after the date this Decree is entered, FDA may take any action(s) it deems appropriate to achieve compliance with the law, including actions under paragraph 22 below, unless an extension is granted pursuant to paragraph 29.

D. Notwithstanding the preceding paragraph, Defendants shall continue to implement and execute all ongoing field actions and/or corrective actions initiated as of the date of entry of this Decree, which Defendants have determined, through their corrective action, risk management, and recall procedures, are necessary. Defendants shall notify FDA of any such actions in writing within ten (10) calendar days of entry of this Decree.

E. Defendants shall commence the implementation of those portions of the initial and/or revised 2009 Corrective Action Plan that were found acceptable by FDA within ten (10) calendar days of receiving FDA's written authorization of the initial and/or revised 2009 Corrective Action Plan, whichever is earlier.

F. Defendants shall, beginning no later than ninety (90) calendar days after the date on which implementation of the 2009 Corrective Action Plan has begun, in whole or in part, and continuing until its completion, submit to FDA monthly written progress reports updating the status of the 2009 Corrective Action Plan. Defendants shall use their best efforts to locate all Alaris System and all other infusion pumps in use by physicians, hospitals, pharmacies, and other user/facilities in the United States and to obtain the cooperation of such users to implement the 2009 Corrective Action Plan. Defendants' methods to locate all such products shall be detailed in the 2009 Corrective Action Plan and be appropriate based upon variations in the products' distribution.

G. Defendants shall complete the implementation of the 2009 Corrective Action Plan by February 2010, unless otherwise specified in the approved 2009 Corrective Action Plan.

ALL CARDINAL 303 INFUSION PUMPS

18. The remaining paragraphs (paragraphs 19-35) shall apply to all infusion pumps manufactured by or for Defendant Cardinal 303, including, but not limited to, the SE infusion pumps and the Alaris System and all other infusion pumps, including all components and parts thereof (hereafter, collectively, "Cardinal 303 infusion pumps"). "Cardinal 303 infusion pump facilities" shall refer to all of Defendant Cardinal 303's facilities, both domestic and foreign, that design, manufacture, process, pack, repack, label, hold, or distribute any Cardinal 303 infusion pump.

A. If, after the entry of this Decree, Defendants establish any additional Cardinal 303 infusion pump facilities, Defendants shall notify FDA in writing of the new facility's name and address within five (5) calendar days of its establishment.

19. A. Within ten (10) calendar days after entry of this Decree, Defendant Cardinal 303 shall retain at its expense an independent person or persons (the "Recall Expert"), who is qualified by education, training, and experience to review Defendant Cardinal 303's recall

procedures and the adequacy of all recalls involving any of the Cardinal 303 infusion pumps, and who is familiar with Cardinal 303's infusion system operations, manufacturing, and design. The Recall Expert shall be without personal or financial ties (other than a consulting agreement between the parties) to any officer or employee of Defendant Cardinal 303 or their immediate families. Defendants shall notify FDA in writing of the identity of the Recall Expert within ten (10) calendar days of retaining that person or the date this Decree is entered, whichever is later. The Recall Expert may be the same person identified as the Expert in paragraphs 12(B) or 16(A) above.

B. Within one hundred (100) calendar days after entry of this Decree, the Recall Expert shall:

i. perform a comprehensive inspection of Defendant Cardinal 303's recall procedures and all ongoing recalls involving any of Cardinal 303's infusion pumps and/or their components and parts thereof, and certify in writing to FDA: (a) that he or she has inspected Defendant Cardinal 303's recall procedures; (b) whether Defendant Cardinal 303's recall procedures are in compliance with the Act, its implementing regulations, and this Decree; (c) the current status of all ongoing recalls involving Cardinal 303's infusion pumps and/or their components and parts thereof; (d) whether Defendant Cardinal 303 should take any further remedial action(s) with respect to any recalls involving Cardinal 303 infusion pumps; and (e) that Defendant Cardinal 303 shall ensure that remedied /corrective actions taken in fact correct the problems identified in recalls.

ii. perform a comprehensive inspection of Defendant Cardinal 303's risk analysis and correction and removal procedures (21 C.F.R. Part 806) and certify in writing to FDA that he or she has inspected these procedures and whether these procedures are in compliance with the Act, its implementing regulations, and this Decree.

iii. To avoid duplication of efforts, if the Recall Expert is the same person identified as the Expert in paragraphs 12(B) or 16(A) above, the Recall Expert's report may refer, if appropriate, to a prior Expert certification report completed pursuant to paragraphs

12(C) or 16(B). If a reference to a prior certification report is made, the Recall Expert shall identify the specific page(s) within the referenced report where the supporting evidence is located. In such case, the Recall Expert may submit one certification to FDA that certifies which specific requirements for the Recall Expert certification set forth in subparagraph 19(B) above have been met.

20. After Defendants have complied with paragraphs 12(A)-(E) and FDA has notified Defendants in writing pursuant to paragraph 12(F) and after Defendants have complied with paragraphs 16(A)-(C) and any violations cited in FDA's Notice are corrected pursuant to paragraph 16(D), Defendant Cardinal 303 shall retain an independent person or persons (the "Auditor") at Defendant Cardinal 303's expense to conduct audit inspections of all Defendant Cardinal 303 infusion pump facilities not less than once every six (6) months for a period of one (1) year and not less than once every twelve (12) months for a period of three (3) years thereafter, for a total of four (4) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to any of Defendant Cardinal 303's officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in paragraphs 12(B) or 16(A) above.

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendant Cardinal 303's infusion pump operations are operated and administered in compliance with 21 U.S.C. §§ 351(h) and 352(t)(2), 21 C.F.R. Parts 803, 806, and 820, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than thirty (30) calendar days after the date the audit inspections are completed. If any Audit Reports identify deviations from 21 U.S.C. §§ 351(h) and/or 352(t)(2), 21 C.F.R. Parts

803, 806, and/or 820, and/or this Decree, FDA may, in its discretion, require that the four (4) year auditing cycle be extended for a length of time not to exceed four (4) years. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at their facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

i. Notwithstanding the requirement in the preceding paragraph, Cardinal 303's Gemini infusion pump is only subject to the post-market requirements of 21 C.F.R. 803, 806, and 820 as set out in paragraph 16(B)(vii) above. If the Gemini infusion pump becomes subject to the requirements set forth in subparagraph 16(B) above, the Gemini infusion pump shall be subject to all of the requirements set forth in subparagraph 20(A) above.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty-five (35) calendar days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty-five (35) calendar days, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, propose a schedule for completing corrections ("Audit Correction Schedule") and provide justification for the additional time. Any such Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Within thirty-five (35) calendar days of Defendants' receipt of an Audit Report, or within the time period provided in an Audit Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within ten (10) calendar days of the beginning of that review, the Auditor shall report in writing to FDA and Defendants whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

21. Upon entry of this Decree, Defendants and each and all of their officers, directors, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in

active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, for so long as such persons are in positions of responsibility with Defendant Cardinal 303 or any of Defendant Cardinal 303's franchisees, subsidiaries, affiliates, and/or "doing business as" entities are permanently enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly:

A. causing the introduction or delivery for introduction into interstate commerce of any Cardinal 303 infusion pump manufactured by or for Defendant Cardinal 303 that is adulterated within the meaning of 21 U.S.C. §§ 351(c) or 351(h) or misbranded within the meaning of 21 U.S.C. § 352(t)(2); and

B. causing any Cardinal 303 infusion pump held for sale after shipment of one or more of its components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 351(c) or 351(h) or misbranded within the meaning of 21 U.S.C. § 352(t)(2).

22. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analysis of samples, a report or data prepared or submitted by Defendants, the Expert, the Recall Expert, or the Auditor pursuant to this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree or the Act, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions with respect to any Cardinal 303 infusion pumps or components or parts thereof located in or to be distributed into the United States. Such actions may include, but are not limited to, the following:

A. Cease designing, manufacturing, processing, packing, repacking, labeling, holding, storing, distributing, installing and/or servicing any Cardinal 303 infusion pumps or components or parts thereof;

B. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

C. Submit additional reports or information to FDA;

D. Recall, at Defendant Cardinal 303's sole expense, any adulterated or misbranded Cardinal 303 infusion pumps or components or parts thereof manufactured, distributed, or sold by Defendant Cardinal 303 or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;

E. Issue a safety alert, public health advisory and/or press release; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants into compliance with Act, its implementing regulations, and this Decree.

23. A. Any order issued by FDA pursuant to paragraph 22 shall be issued by the appropriate FDA District Director, and shall specify the deficiencies or failures giving rise to the order. Unless a different time frame is specified by FDA in its order, within fifteen (15) calendar days after receiving an order pursuant to paragraph 22, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific actions taken or to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If any Defendant notifies FDA that he does not agree with FDA's order, within fifteen (15) calendar days after receiving Defendant's response, FDA will review Defendant's notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. This written notification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and, if they so choose, bring the matter before this court on an expedited basis. Defendants shall continue to

diligently implement FDA's order while the matter is before the Court and unless and until the court reverses, stays, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 33.

24. Any cessation of operations described in paragraphs 22–23 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraphs 22-23 shall be borne by Defendant Cardinal 303 at the rates specified in paragraph 26.

25. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendant Cardinal 303 infusion pump facilities and take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted: access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendant Cardinal 303's materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all devices. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. FDA will provide Defendants with a receipt for any samples taken pursuant to 21 U.S.C. § 374 and, upon Defendants' request and at Defendant Cardinal 303's own expense, with copies of any photographs or video recordings made. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

26. Defendant Cardinal 303 shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all inspectional costs necessary to evaluate Defendants' compliance with the terms of paragraphs 14 and 17. The costs of such

inspections shall be borne by Defendant Cardinal 303 at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $85.49 per hour and fraction thereof per representative for inspection work; $102.49 per hour or fraction thereof per representative for analytical or review work; $0.55 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. FDA shall submit a reasonably detailed bill of costs to Defendant Cardinal 303 at the address specified in paragraph 30. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the court.

27. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of its officers, directors, agents, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities) with responsibility for the manufacture and quality of all Cardinal 303 infusion pumps (hereafter, collectively referred to as "Associated Persons"). Within twenty (20) calendar days of the entry of this Decree, Defendants shall provide a copy of this Decree to all of Defendant Cardinal 303's employees involved in the designing, manufacturing, processing, packing, repacking, labeling, holding, storing, distributing, installing and/or servicing of all Cardinal 303 infusion pumps, by prominently posting a copy of this Decree in the employee common areas at all Cardinal 303 infusion pump facilities where such employees are located and on Defendant Cardinal 303's intranet Website in such a manner to ensure that it will be viewed by such employees. Defendant Cardinal 303 shall ensure that the Decree remains posted on its intranet and in these employee common areas for no less than twelve (12) months. Within thirty-five (35) calendar days of the date of entry of this Decree, Defendant Cardinal 303 shall provide to FDA an affidavit of compliance, stating the fact

and manner of compliance with the provisions of this paragraph and identifying the names and positions of all Associated Persons who have received a copy of this Decree and the manner of notification. In the event that Defendant Cardinal 303 becomes associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

28. Defendant Cardinal 303 shall notify the District Director, FDA Los Angeles District Office, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of Defendant Cardinal 303 or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendant Cardinal 303 shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendant Cardinal 303 shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

29. Defendants may at any time petition FDA in writing to extend any deadline provided for herein, and FDA may grant such extension without seeking leave of court. However, any such petitions shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

30. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to the District Director, FDA Los Angeles District Office, 19701 Fairchild, Irvine, California 92612. All notifications, correspondence, and communications required to be sent to Defendants by the terms of this Decree shall be addressed to Vice President, Quality and Regulatory Affairs, Cardinal Health 303, Inc., 10020 Pacific Mesa

Blvd., San Diego, California 92121.

31. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendant Cardinal 303 shall pay to the United States of America the sum of fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues and an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree. The amount of liquidated damages in this paragraph shall not exceed fifteen million dollars ($15,000,000) in any one calendar year.

32. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendant Cardinal 303 shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

33. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

34. If Defendants petition the court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained at Defendant Cardinal 303 infusion pump facilities a state of continuous compliance with the Act, its implementing regulations, and this Decree for the sixty (60) months preceding the petition, Plaintiff will not oppose such petition.

35. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

So ordered the ____ day of _____, 2009.

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree:

FOR CLAIMANT/DEFENDANTS:

DAVID L. SCHLOTTERBECK, individually and on behalf of Cardinal Health 303, Inc., formerly known as Alaris Medical Systems, Inc., Chairman and Chief Executive Officer

DWIGHT WINSTEAD, individually and on behalf of Cardinal Health 303, Inc., formerly known as Alaris Medical Systems, Inc., President and Chief Operating Officer

DONALD M. ABBEY, individually and on behalf of Cardinal Health 303, Inc., formerly known as Alaris Medical Systems, Inc., Senior Vice President, Quality and Regulatory Affairs

PETER S. SPIVACK (Cal. Bar No. 136909)
Counsel for Cardinal Health 303, Inc., formerly known as Alaris Medical Systems, Inc., David L. Schlotterbeck, Dwight Winstead, and Donald M. Abbey

FOR PLAINTIFFS:

KAREN P. HEWITT
United States Attorney
Southern District of California

By:
THOMAS STAHL
Assistant United States Attorney
880 Front Street, Room 6293
San Diego, California 92101

EUGENE M. THIROLF
Director
Office of Consumer Litigation

ALLAN GORDUS
Office of Consumer Litigation
United States Department of Justice

OF COUNSEL:

DAVID S. CADE
Acting General Counsel

JEFFREY SENGER
Acting Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
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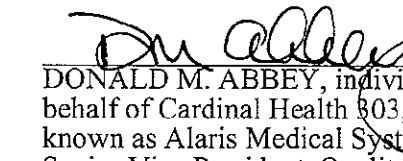

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THOMAS STAHL
Assistant United States Attorney
880 Front Street, Room 6293
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Assistant United States Attorney
880 Front Street, Room 6293
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PETER S. SPIVACK (Cal. Bar No. 136909)
Counsel for Cardinal Health 303, Inc., formerly known as Alaris Medical Systems, Inc., David L. Schlotterbeck, Dwight Winstead, and Donald M. Abbey

FOR PLAINTIFFS:

KAREN P. HEWITT
United States Attorney
Southern District of California

By: Tom Stahl
THOMAS STAHL SBN: 78291
Assistant United States Attorney
880 Front Street, Room 6293
San Diego, California 92101

EUGENE M. THIROLF
Director
Office of Consumer Litigation

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Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

MICHELE LEE SVONKIN
Associate Chief Counsel

U.S. Department of Health and Human Services
Office of the General Counsel
5600 Fishers Lane
Rockville, Maryland 20857
(301) 827-2803